

Message Text

UNCLASSIFIED

PAGE 01 STATE 130061
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 MED-03 /029 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/CE:KAKURZE(INFO)

-----062236Z 089136 /73

P 062142Z JUN 77
FM SECSTATE WASHDC
TO AMEMBASSY BONN PRIORITY

UNCLAS STATE 130061

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, GW

SUBJECT: FDA ADVISORY - RECALL B-012-7(HBSAG POSI-
TIVE)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: (A) LYOPHILIZED HUMAN PLASMA IN BULK
FIBER BOARD DRUMS AND (B) FROZEN HEPARINIZED PLASMA, DEF-
IBRINATED IN 3 LITER PLASTIC CONTAINERS. PRODUCT INTEND-
ED FOR IN-VITRO DIAGNOSTIC MANUFACTURING.

PRODUCT IDENTIFICATION: PRODUCTS ARE DISTRIBUTED UNDER
BPC LABEL, BPC INC., WEST CHESTER, PA.

(A) LYOPHILIZED HUMAN PLASMA, IN BULK FIBER DRUMS,
BATCH NUMBERS 600, 603, 604, AND 60-

(B) FROZEN HEPARINIZED PLASMA, DEFIBRINATED IN 3 LITER
CONTAINERS, LOT NO. 506, CONTAINER NO. S 1 THRU 167
(APPROX, 500 LITERS)

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MANUFACTURER/RECALLING FIRM:

BPC, INC.,
4 S. WAYNE ST, WEST CHESTER, PA 19380

COMPONENTS WERE RECEIVED FROM NUMEROUS BLOOD BANKS, HOS-

PITALS AND BROKERS. SOURCE OF SUPPLY CANNOT BE DOCUMENTED
IN ALL INSTANCES.

2. REASON FOR RECALL: PRODUCTS FOUND TO BE HBSAG RE-
ACTIVE (HEPATITIS B SURFACE ANTIGEN). RESULTS OF TESTS
PERFORMED BOTH BY BPC AND THE CONSIGNEES FOR THE PRODUCTS
CONFIRMED PRODUCTS TO BE HBSAG REACTIVE. FDA RECEIVED AN
ANONYMOUS COMPLAINT THAT FIRM WAS SHIPPING HEPATITIS POS-
ITIVE MATERIAL AND INITIATED AN INSPECTION. FIRM ADVISED
FDA OF DETAILS DURING INSPECTION OF 3/11/77.

3. POST REQUESTED TO CONTACT CONSIGNEE TO DETERMINE IF
THEY HAVE QUARANTINED, AS PER TWX 4/19/77, LHP AND HPD
MATERIAL AND DESTROYED IT.

4. CONSIGNEE AS FOLLOWS:

BOEHRINGER MANNHEIM
BIOCHEMICA WERK
TUTIZING ZOLLAMT WEILHEIM
81 20 WEILHEIM/0BB
FEDERAL REPUBLIC OF GERMANY VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, BLOOD, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 06-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE130061
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770201-0700
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770686/aaaacxly.tel
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Litigation Codes:
Litigation History:
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Message ID: 982f3984-c288-dd11-92da-001cc4696bcc
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Original Classification: UNCLASSIFIED
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Original Previous Classification: n/a
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Previous Classification: n/a
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Review Date: 26-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2259241
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - RECALL B-012-7(HBSAG POSITIVE)
TAGS: OGEN, ETRD, EIND, TBIO, GE
To: BONN
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/982f3984-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
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